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New Strategies for Food and Drug Safety

Taiwan Food and Drug Administration (TFDA) has taken up the mission of constructing a sound and safe food and medicinal products management system and building a trustworthy public food and medicinal products consumer environment. Under the vision of “Safe and effective medicinal products, safe and healthy food,” TFDA upholds the core concepts of food and medicinal products “Total product life cycle management,” and serves as the guardian of public health through the management of sources, manufacturing, and circulation.

Section 1

Food Management Overview

To maintain public confidence in food sanitation and safety, TFDA collects and refers to international standards and techniques, promulgates and revises regulations related to “*Act Governing Food Safety and Sanitation*”(abbreviated as the *Food Safety Act*), strengthens inspection competence and volume, and develops novel inspection methods. TFDA also actively promotes management, including food business registration system, food traceability system, food businesses self-management, border inspection of imported food, specific food registration, system updates and source control, etc. TFDA works with local governments and Health Bureaus to carry out programs for the inspection, sampling and testing, as well as post-marketing surveillance of food products, in order to prevent defective products from listing and to ensure food hygiene, safety and quality.

In addition, TFDA continues promoting “Five-point Food Safety Policy” (Figure1-1). Industry self-regulation, government management and civil participation are three major forces behind the effective implementation of the policy to complete the farm-to-table management process as well as to build up a strong and credible food safety system in which the consumers may purchase with confidence. For food management overview (Figure1-2).

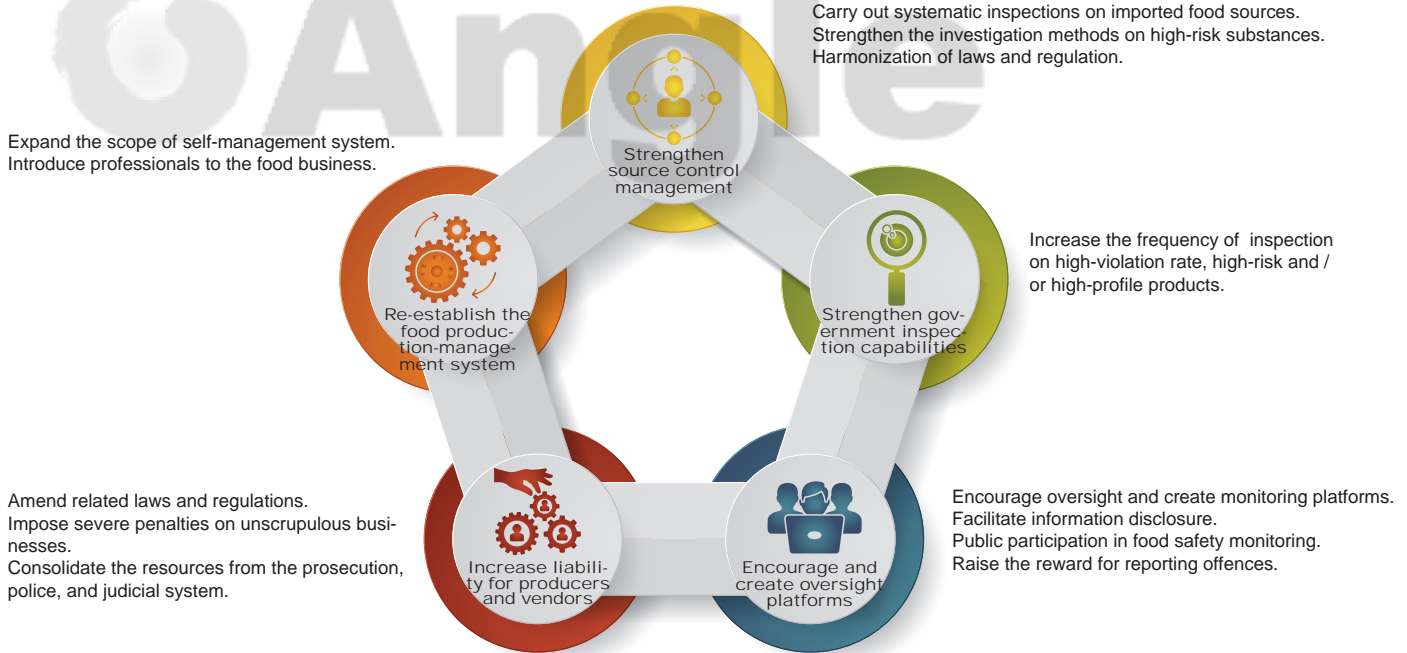


Figure1-1 Five-point Food Safety Policy

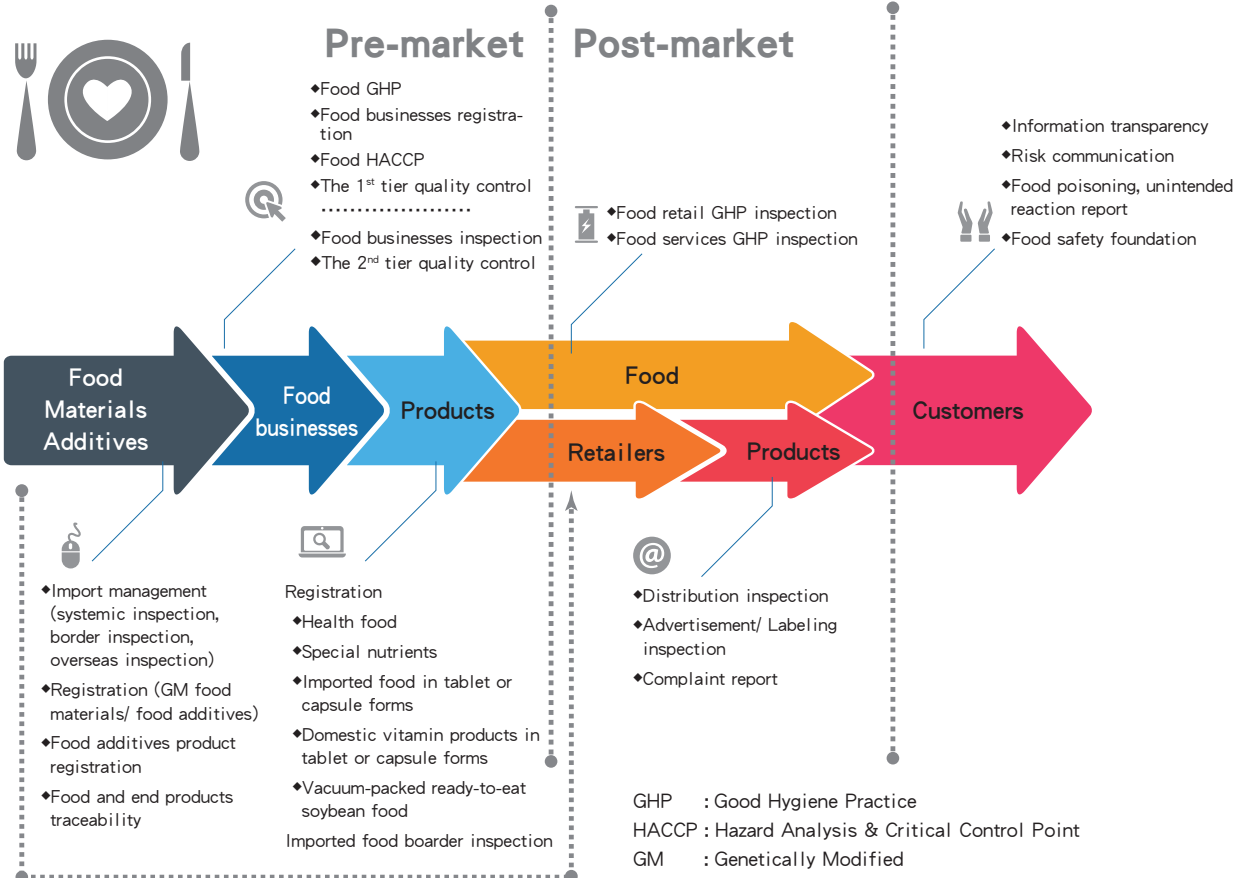


Figure1-2 Food life cycle management

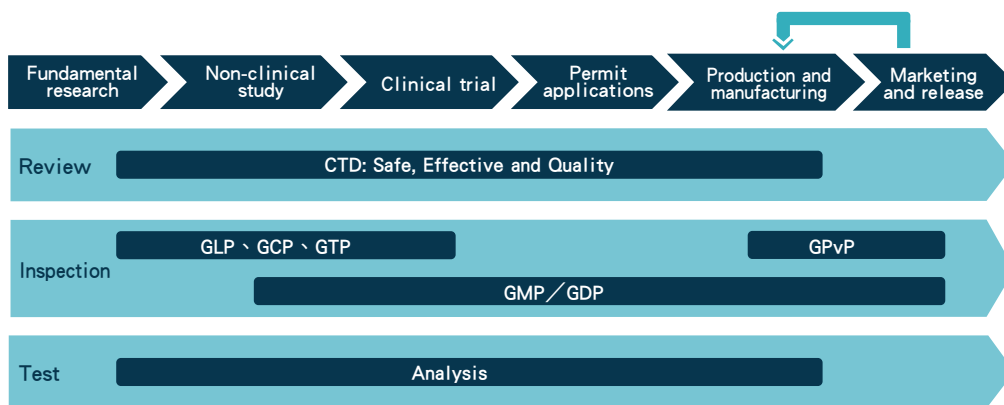
Section 2 Overview of Drugs and Cosmetics Management

In order to promote the safety and quality of medicinal products, and to facilitate the development of the biotechnology industry, TFDA established a regulatory environment in line with international trends to respond to global market development and law harmonization. At the same time, TFDA continued on advancing drug review capacity and improving product shortage reporting/assessment system; activate search potential cases and establish counseling projects to expedite the production of innovative medical devices and medicinal products in Taiwan, and thus achieve a stable supply chain and provide industry consultation/counseling services and complete product review system. TFDA also strengthened product manufacturing, distribution management, and quality surveillance, to establish medicinal product traceability and follow-up system and accomplished an overall safety and quality control of medicinal products and cosmetics.

Moreover, TFDA is committed to diversify pharmaceutical affairs services, and create a correct and supportive educational environment to increase the awareness of safe drug, medical device, and cosmetics use of the public.

1. Medicinal products management framework

The medicinal product life cycle from research and development to market release include the following steps: fundamental research, non-clinical studies, clinical trials, license applications, manufacturing, and market distribution. Each step should be in compliance with various



- CTD : Common Technical Document
- GLP : Good Laboratory Practice
- GCP : Good Clinical Practice
- GTP : Good Tissue Practice
- GPvP : Good Pharmacovigilance Practice
- GMP : Good Manufacturing Practice
- GDP : Good Distribution Practice

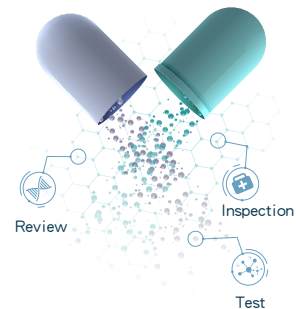
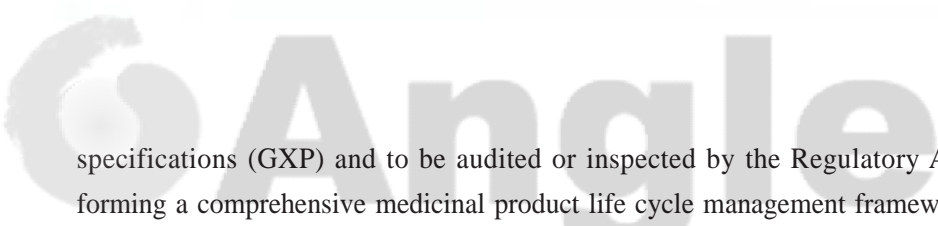


Figure1-3 A comprehensive medicinal product life cycle management framework



specifications (GXP) and to be audited or inspected by the Regulatory Agency, and thereby forming a comprehensive medicinal product life cycle management framework. To ensure study data integrity and reliability, GLP and GCP compliance are required for non-clinical studies and clinical trials respectively. As for the manufacturing processes, GMP shall be followed. TFDA conducted GCP, GLP and GMP audit/inspection following international standard, and where necessary, pre-market release inspection and analysis, as well as post-marketing sampling tests, would be carried out to ensure continuing compliance with Good Pharmacovigilance Practice (GPvP). These measures would improve measures for medicinal product quality and safety surveillance and achievement of all medicinal product life cycle management objectives (Figure 1-3).

2. Controlled drugs management framework

Prescription drug abuse has been a common problem faced by various countries around the world, suggesting that abuse or illegal distribution may lead to major damage caused by addiction problems, which would be as serious as drug issues. Therefore, Prescription drug management is a critical measure to prevent abuse and to ensure public health.

According to “Single Convention on Narcotic Drugs (1961),” “Convention on Psychotropic Substances (1971)” and “Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of the United Nations (1988).” Taiwan has imposed controls on narcotics, psychotropic substances and their preparations through the “Narcotics Hazard Prevention Act.” However, due

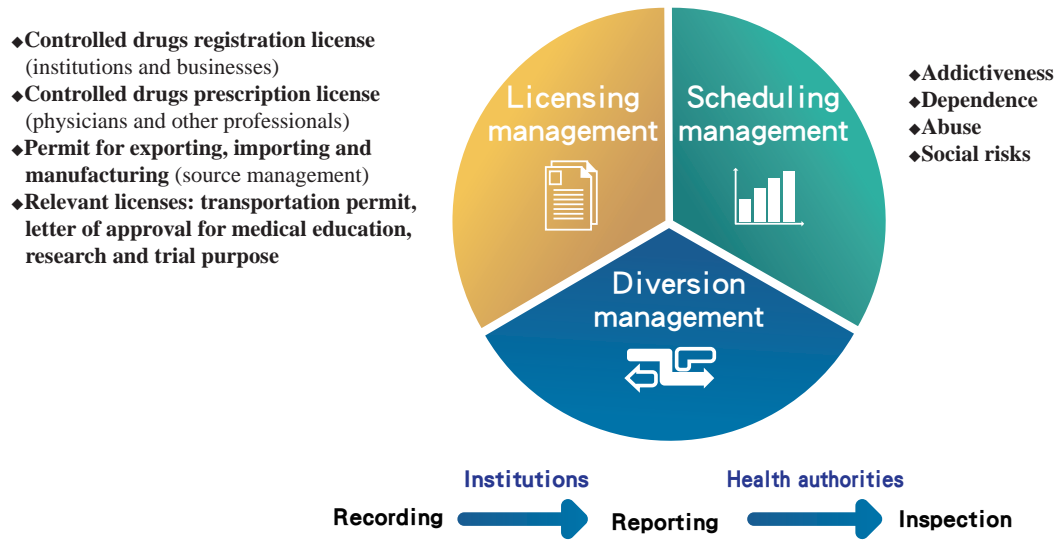
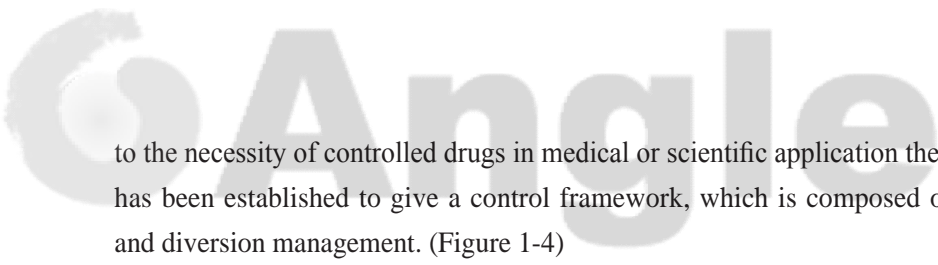


Figure1-4 Controlled drugs management framework



to the necessity of controlled drugs in medical or scientific application the “*Controlled Drugs Act*” has been established to give a control framework, which is composed of licensing, scheduling, and diversion management. (Figure 1-4)

3. Medical devices management framework

The medical device industry is poised to become Taiwan's leading biotech industry in terms of development potential, given its rapid developments in technology and growing demands for healthcare technologies. In response to the growing prospects of the medical device industry in Taiwan, the TFDA has established a Total Product Life Cycle (TPLC) management policy for medical devices (Figure 1-5) that includes harmonization with international standards and regulations, production source control, pre-market control, post-market surveillance, management of pharmaceutical companies and product distribution channels, and provision of professional counseling services. The purpose of the TPLC policy is to effectively control the safety, performance, and quality of medical devices, and to promote the developments of Taiwan's biotech and pharmaceutical industry, in order to create an environment beneficial for consumers, industry, and government.

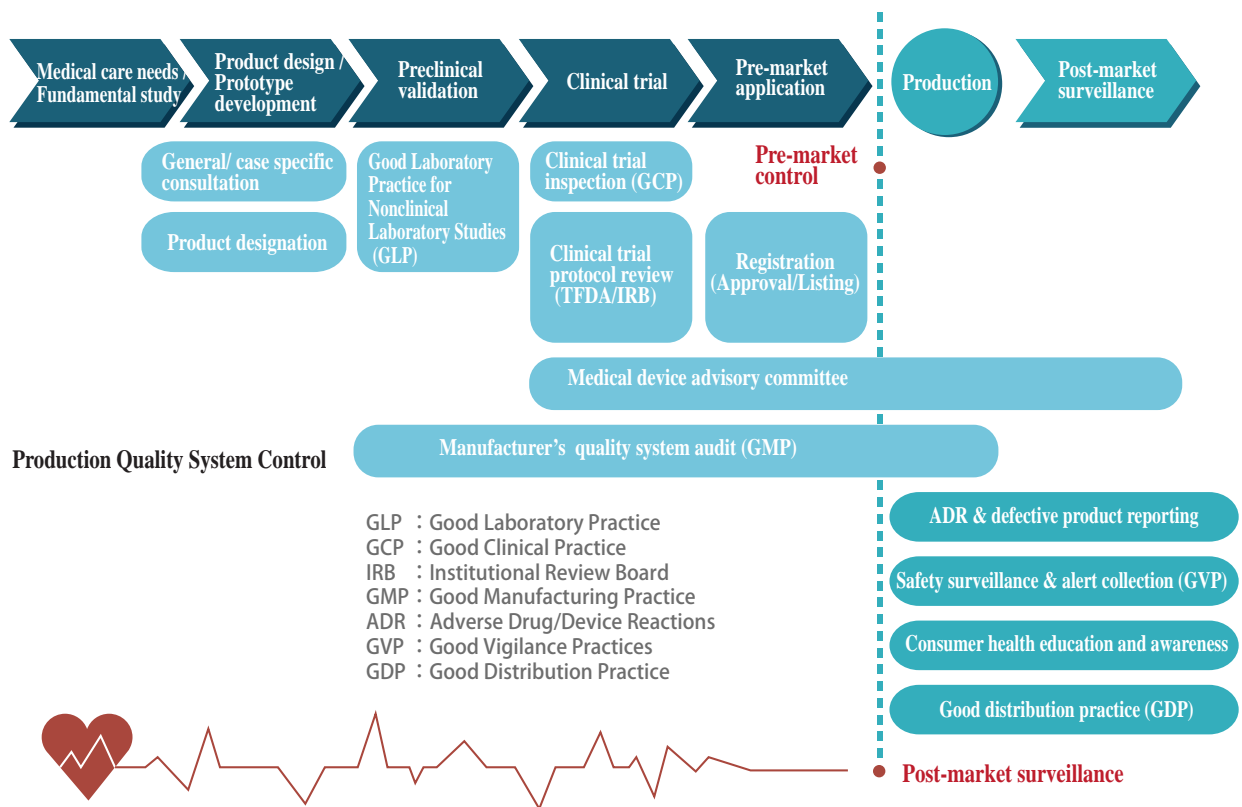


Figure1-5 Total product life cycle management policy for medical devices



Angle

4. Cosmetics management framework

The current cosmetics management system is divided into production source control, pre-market management, and post-market surveillance. (Figure 1-6) Source control management includes ensuring that manufacturers comply with Establishment Standards for Cosmetics Manufactory and promoting voluntary Good Manufacturing Practice (GMP) for cosmetics. Pre-market management includes registrations of medicated cosmetics. And post-market surveillance focuses on implementing cosmetics quality surveillance programs with joint audits spanning multiple counties and cities, establishing a product adverse event reporting system for cosmetics, monitoring of domestic and global cosmetic safety alerts regularly, and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.

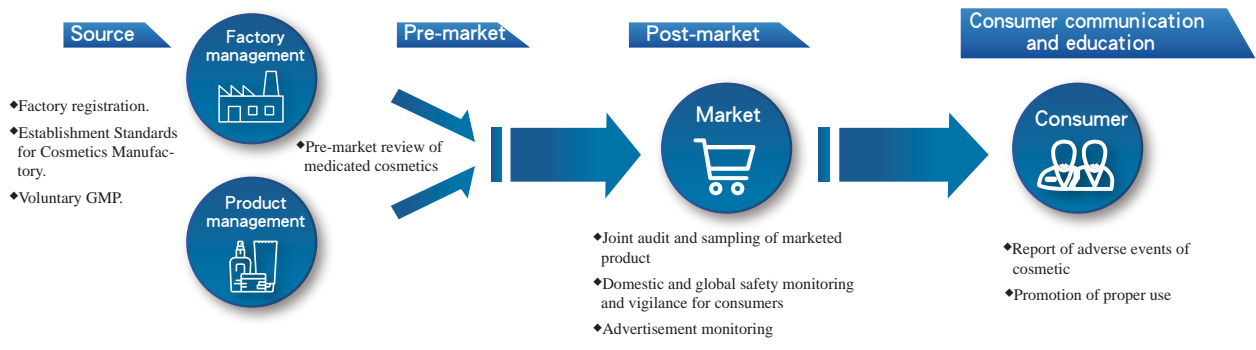


Figure1-6 Cosmetics management framework



Note: The amended draft of the Cosmetic Hygiene and Safety Act was reviewed and approved by the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan on December 20, 2017. On December 29 of the same year, the Legislative Yuan decided to send the draft for negotiation among party caucuses. The amendment was announced by the President through the Hua-Zong(I)-I-Zi No. 10700045851 order on May 2, 2018, with the enforcement date to be determined by the Executive Yuan. In the future, the term “medicated cosmetics” will be changed to “specific purpose cosmetics” and the product notification and product information file will replace the existing pre-marketing registration system for medicated cosmetics. There is a five-year transition period in place for the switch from the registration system to the new one.